



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

April 5, 1999

1442 '99 APR -7 19:50

Abu Quamruzzaman  
178-10 Wexford Terr.  
Apt. 5C  
Jamaica, NY 11432

Re: Docket No. 93N-0462

Dear Mr. Quamruzzaman,

This is in response to your letter dated March 30, 1999, in which you seek clarification regarding your debarment. Specifically, you wish to know whether you can work in (1) a pharmaceutical company producing OTC products, (2) a company producing vitamins and herbal products, or (3) a company producing cosmetic products.

The terms of your debarment state that you are prohibited *from providing services in any capacity to a person*, including a company, *that has an approved or pending drug product application*. The term *application* refers to certain formal submissions to the agency such as New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and a few others. Most, though not all, of the products in the three categories to which you refer are marketed without such applications. So it is possible, but not certain, that you could work for a company of the type you describe and not be in violation of your debarment. There are at least two things of which you should be particularly aware. First, please note the phrase "in any capacity" in the first sentence of this paragraph -- this means you may not work for a company if it has an approved or pending drug product application regardless of what your job would be or even if the division you would work for does not submit such applications. Second, you should be aware that circumstances outside your control could alter whether or not you are in violation of your debarment. For example, recently a debarred individual began working for a small company that produces vitamin supplements. For six months he was not in violation of his debarment. But when a large pharmaceutical company purchased the small company, he had to leave the company.

I hope this information is helpful.

Sincerely yours,

Dave Read  
Acting Director, Regulatory Policy Staff (HFD-7)  
Center for Drug Evaluation and Research

cc: HFA-305/Docket No. 93N-0462

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